



## CERTIFICATE OF ANALYSIS

PRODUCT:	RIFAXIMIN	QUANTITY:	200KG
BATCH NO.:	20090322	MFG. DATE:	03/22/2009
PACKING:	25KG/DRUM	EXP. DATE:	03/21/2011
FOUNDATION:	IN-HOUSE STANDARD	DATE OF REPORT:	03/30/2009

Sr No.	Items	Specifications	Observation
01	<b>Description *</b>	Orange to reddish coloured powder.	Reddish orange powder
02	<b>Solubility</b>	Soluble in chloroform & in methanol, in ethyl acetate & in acetone.	Conforms
03	<b>Identification</b>	A. The Infra-red absorption spectrum sample should concordant with the spectrum obtained from Rifaximin WRS. B. The retention time of the major peak in the chromatogram of standard preparation as obtained under assay test.	Complies
04	<b>Water Content *</b>	Between 3.50 % to 6.50 % w/w	4.20%
05	<b>Heavy Metals</b>	NMT 0.002 % w/w	Conforms
06	<b>Sulphated Ash</b>	NMT 0.20 % w/w	0.04%
07	<b>Related Substances *</b>		
	a) Rifamycin-O	NMT 0.50 % w/w	NA
	b) 2-Amino-4methyl pyridine	NMT 0.50 % w/w	NA
	c) 25-desacetyl rifaximin	NMT 0.50 % w/w	Conforms
	d) Any other individual impurity	NMT 0.50 % w/w	0.29%
	e) Total impurities	NMT 2.50 % w/w	0.74%
08	<b>Assay *</b>	Between 97.0 - 102.0 % w/w (On anhydrous basis)	99.26%
09	<b>Related Solvent #</b>		
	a) Methanol	NMT 3000 ppm	NA
	b) Ethanol	NMT 5000 ppm	Conforms
	c) Acetone	NMT 5000 ppm	NA
	d) Chloroform	NMT 60 ppm	NA

This is certified that we, the undersigned, have inspected the quality of above-mentioned goods as manufacturer and found the result as following:

Conclusion is up to the Standard of In-house standard



Approved by:

Checked by:

Analysed by: